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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Docket No. 02N–0332

Preparation for the International Conference on Harmonization Meetings in Washington, DC, Including Progress on Implementation of the Common Technical Document; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Meetings in Washington, DC, Including Progress on Implementation of the Common Technical Document" to solicit information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Washington, DC. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Washington, DC, September 9 to 12, 2002, at which discussion of the Common Technical Document and the future of ICH will continue.

Date and Time: The public meeting will be held on September 5, 2002, from 10:30 a.m. to 2 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact: Kimberly Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6801, e-mail: Topperk@cder.fda.gov.

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Registration and Request for Oral Presentation: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations to the contact person by August 29, 2002.

If you need special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the

Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at http://www.ifpma.org/ich1.html

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 1 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by August 29, 2002, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on August 29, 2002, under Docket No. 02N–0332, at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: 8-1-02
August 1, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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